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L CGNE-62-1(1)
EXAMINER

MOODY, P

ART UNIT PAPER NUMBER

26

1804

DATE MAILED:

01/24/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 16 Nov 1993 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire THREE (3) month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 20, 22-28, 30, 33-36, and 43 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 1-19, 21, 29, 31-32, 37-42 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 20, 22-28, 30, 33-36, and 43 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other _____

EXAMINER'S ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5 Claims 20, 22-27, and 33-35 remain rejected under 35 U.S.C. § 102(a) as being clearly anticipated by either Gowda et al or Wu et al.

10 Claims 20, 22-27, and 33-36 remain rejected under 35 U.S.C. § 102(a) as being clearly anticipated by Goldberg et al.

15 Applicant's arguments and the Comai et al Declaration filed 16 November 1993 have been fully considered but they are not deemed to be persuasive. Although signed by all inventors, the Comai et al Declaration does not show possession of the claimed invention prior to the stated date. The Declaration and attached exhibits refer to protoplasts but do not mention plants (claim 36) or constitutive transcription (claim 20).

20 Claims 20, 22-28, 30, 33-36, and 43 remain rejected under 35 U.S.C. § 103 as being unpatentable over Shah et al and Sanders et al taken with Richins et al or Gowda et al or Wu et al or Goldberg et al as applied in the last office action and repeated herein.

25 The primary references disclosed all features of the present invention except for specifying FMV 34S instead of CaMV 35S as an alternative viral promoter. The secondary references disclosed the FMV 34S promoter which was analogous in structure and strong expression characteristics with the well-known CaMV 35S promoter long used in recombinant constructs in transgenic plants. At the time this invention was made, it was obvious to one of ordinary skill in the art to modify the primary references with the teachings of the secondary references in order to express genes of interest with yet another strong viral promoter with a reasonable expectation of success. Thus the invention as claimed was very clearly prima facie obvious as a whole over the prior art in the absence of clear and convincing evidence to the contrary.

40 Applicant's arguments and the Comai et al Declaration filed 16 November 1993 have been considered and the Sanger Declaration (Paper No. 21) has been reconsidered but they are not deemed to

be persuasive. The Comai et al Declaration is not effective against three of the four alternative secondary references for the reasons noted above. Note also that statements by Applicant which urge (page 9, response) that constitutive expression is unknown until tested directly relate to the insufficiency of the Comai et al Declaration.

Insistence by Applicant that Richins et al did not correctly point out the promoter lacks persuasive force as Figure 5 clearly lined up the FMV 34S promoter disclosed by applicant with the CaMV 35S promoter (cf. Figure 5 Richins et al with Figure 1 this specification). The opinion of Sanger (Paper No. 21), an interested party, is also not persuasive particularly in the face of clear teachings by Richins et al of a reasonable expectation that the 34S FMV promoter was a strong promoter. Applicant urges combination with other genes and promoters at page 9 of the response; but other genes and promoters are not relevant to this rejection. If applicant is attempting to question the teachings of the issued patent, sufficient clear and convincing probative evidence has not been provided in support thereof. Secondary references do not have to provide teachings which are supplied by the primary references.

Claims 20, 22-28, 30, 33-36 and 43 remain rejected under 35 U.S.C. § 103 as being unpatentable over Shah et al and Sanders et al taken with Richins et al and Shepherd et al as applied in the last office action and repeated herein.

Each of the primary references disclosed all features of the present invention (including constructs with genes of interest controlled by two different strong, constitutive promoters one of which was a CaMV 35S promoter) but did not identify FMV 34S as an

alternative viral promoter. Richins et al disclosed the FMV 34S promoter sequence and taught that it was analogous to CaMV 35S in position, structure, and function and, likewise, expected to have similar strong expression characteristics. This was echoed by Shepherd et al which taught that FMV was as amenable to cloning manipulation as CaMV. Shepherd et al described the broad host range and high titer achievable with FMV in plant host cells and also compared CaMV and FMV promoters. At the time this invention was made, it was obvious to one of ordinary skill in the art to modify the primary references with the teachings of the secondary references in order to obtain high levels of expression of genes of interest in host plant cells with yet another strong viral promoter source. The extensive comparative analogy drawn with CaMV would have led one of ordinary skill in the art to have reasonably expected to obtain high levels of constitutive expression with analogous FMV promoters. Thus the invention as claimed was very clearly prima facie obvious as a whole over the prior art in the absence of clear and convincing evidence to the contrary.

Applicant's arguments filed 16 November 1993 have been fully considered and the Sanger Declaration (Paper No. 21) has been reconsidered but they are not deemed to be persuasive. It is not clear what applicant is trying to say about titer in the response at page 10. The Examiner's comments were that concern about titer was misplaced and that it was unclear whether applicant was saying that titer was unrelated to promoter strength or was a reason to think that one strain would not have a strong promoter (e.g., ¶ 8-9 seem to be inconsistent with ¶ 10-12). However, titer was not the basis for the rejection and has no relevance beyond that of indicating high levels of expression in plants as was stated in ¶ 10 and 12 of the Sanger Declaration, for example.

The rejection is based upon a combination of references and Shepherd et al need not provide teachings which are provided by Richins et al. Comments made above in relation to Richins et al

are incorporated by reference. Expectations of success do not have to be absolute only reasonable and applicant provides no basis for thinking that these expectations were not reasonable.

The expectedly strong FMV 34S promoter was clearly identified by the cited prior art such that the claimed FMV 34S promoter is the prior art FMV 34S promoter and properties possessed by the claimed FMV 34S promoter are also possessed by the prior art FMV 34S promoter.

No claim was allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to P. Moody (nee Rhodes) at telephone number (703) 308-0196.

P. Moody
January 21, 1994

P. Moody
PATRICIA R. MOODY
PRIMARY EXAMINER
GROUP 1800